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UNITED STATES DISTRICT COURT DISTRICT OF NEW JERSEY

IN RE MERCK & CO., INC. VYTORIN/ZETIA SECURITIES LITIGATION

IN RE SCHERING-PLOUGH CORPORATION/ENHANCE SECURITIES LITIGATION 08-CV-2177 (DMC) (JAD)

08-CV-397 (DMC) (JAD)

THE MERCK AND SCHERING DEFENDANTS' MEMORANDUM OF LAW IN SUPPORT OF THEIR MOTION IN LIMINE NO. 4: TO PRECLUDE PLAINTIFFS FROM OFFERING: (A) CERTAIN EVIDENCE CONCERNING THE MERCK/SCHERING-PLOUGH MERGER, (B) EVIDENCE CONCERNING THE PERSONAL WEALTH OR COMPENSATION OF DEFENDANTS OR OF EMPLOYEES OF THE UNDERWRITER DEFENDANTS, AND (C) DR. JAMES STEIN'S DECISION TO "CUT TIES" WITH MERCK

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PRELIMINARY STATEMENT

The Merck and Schering Defendants bring this motion *in limine* to preclude Plaintiffs from offering certain evidence that is irrelevant and unfairly prejudicial. In particular, Defendants seek to preclude evidence concerning:

(1) payments made to certain of the Schering Defendants in connection with the November 2009 merger between Merck and Schering-Plough, along with evidence concerning the reasons for that merger; (2) the personal wealth or compensation of Defendants or employees of the Underwriters; and (3) the decision by Dr. James Stein, a member of an expert panel that reviewed data quality issues in the ENHANCE trial, to later "cut ties" with Merck.

Defendants announced the results of the ENHANCE clinical trial in January 2008. Merck and Schering agreed to merge more than a year later, in March 2009, and the merger was completed in November 2009. In connection with the merger, certain of the Defendants who are former Schering executives received substantial separation payments. There is no evidence that the merger or

The "Underwriters," who join in Section III of this motion in limine, are defendants ABN AMRO Rothschild LLC; Banc of America Securities LLC; Banca IMI SpA; BBVA Securities Inc.; Bear, Stearns & Co. Inc. (now J.P. Morgan Securities LLC); BNP Paribas Securities Corp.; BNY Capital Markets, Inc.; Citigroup Global Markets, Inc.; Credit Suisse Securities (USA) LLC; Daiwa Capital Markets America Inc.; Goldman, Sachs & Co.; ING Financial Markets LLC; J.P. Morgan Securities LLC; Mizuho Securities USA Inc.; Morgan Stanley & Co. LLC; Santander Investment Securities Inc.; Utendahl Capital Partners, L.P.; and The Williams Capital Group, L.P.

the separation payments had anything to do with the ENHANCE study. Evidence concerning the separation payments and the reasons for the merger, therefore, have no relevance to the issues in these cases. Evidence concerning these issues would also be unfairly prejudicial, confusing, and a waste of time. Jurors might be unfairly prejudiced against the Defendants who received substantial payments in connection with the merger. And they may speculate that there was some link between the merger, the payments, and the allegations concerning the ENHANCE trial, even though there is no such connection.

Similarly, Plaintiffs should be precluded from offering evidence of the compensation or personal wealth generally of Defendants or of employees of the Underwriters. It is well-established that such evidence is irrelevant and may unfairly prejudice jurors.

Finally, the evidence concerning Dr. Stein is also irrelevant and unfairly prejudicial. In 2008, Dr. Stein decided to sever ties with five pharmaceutical companies, including Merck. Dr. Stein's severed ties with Merck for reasons unrelated to ENHANCE – namely, allegations against Merck in connection with Vioxx (which has nothing to do with ENHANCE), and Dr. Stein's own concerns about academic independence. His decision to cut ties with Merck is therefore irrelevant to any issue in these cases. It is also unfairly prejudicial,

because it suggests that Dr. Stein had formed a negative opinion of Merck, and because it would inject issues concerning Vioxx into these cases.

BACKGROUND FACTS

The Merck-Schering Merger

As the Court is aware, these cases concern the ENHANCE clinical trial, which was designed to test the efficacy of the cholesterol-lowering drug Vytorin. Vytorin was produced by a joint venture between Merck and Schering-Plough. At the time of the ENHANCE trial and throughout the class periods in these cases, Merck and Schering were separate companies, except for their collaboration on the joint venture that produced Vytorin.

On March 8, 2009, nearly a year after the close of the class periods in these cases, Merck and Schering agreed to a merger. (Kravitz Aff. II Ex. 34.) The merger was completed on November 3, 2009. (*Id.*)

As disclosed in the Notice to Merck and Schering shareholders concerning the merger, certain Schering executives who are among the Defendants in the Schering case received substantial separation payments in connection with the merger. (Notice of Shareholder Meeting) (Kravitz Aff. II Ex. 35, at p. 91). In April 2009, a shareholder suit was filed in this Court challenging the proposed merger, focusing in particular on the separation payments. (City of Edinburgh

Complaint) (Kravitz Aff. II Ex. 36.) The Carella, Byrne firm, which is lead counsel in the Schering case, was one of the firms that filed that action. (*Id.*)

Dr. Stein's Emails and Testimony Concerning "Severing Ties"

Dr. James Stein is a doctor at the University of Wisconsin School of Medicine and Public Health. He was a member of a panel that Merck/Schering-Plough convened to review data quality issues that arose during the ENHANCE trial. During discovery, Dr. Stein produced emails from April 2008 and April 2009 stating that he was "severing ties" with several pharmaceutical companies, including Merck and Schering. (PX-380; PX-381) (Kravitz Aff. II Exs. 37 & 38). Dr. Stein testified about these emails and about his decision to "sever ties" in his deposition in April 2011. (Stein Dep. 40:9 – 44:19) (Kravitz Aff. II Ex. 39).

The April 11, 2008 email was from Dr. Stein to Patrick McBride, one of Dr. Stein's colleagues at the University of Wisconsin. (PX-381.) In it, Dr. Stein wrote: "You should see what is coming out next week about Merck and Vioxx – 2 stories below. And with ENHANCE – I am done. I have officially notified Merck today to cancel my contracts with them – speaker's bureau, advisory boards, etc. I am completely severing ties." Attached to the email were two news releases concerning Merck and rofecoxib, the generic name for Merck's anti-inflammatory drug Vioxx.

Dr. Stein testified that this email "was part of a series of ongoing interactions [with Dr. McBride] that the two of us had working out what we felt would be appropriate or inappropriate interactions with pharmaceutical companies given our university positions." (Stein Dep. at 43:3-7) He also testified that, when he wrote "and with ENHANCE I am done," he meant that "at that time I felt that everything was done with ENHANCE and I would never have to come back and visit that study again." (*Id.* at 43:16-20.)

The April 22, 2009 email was from Dr. Stein to John Fauber, a reporter at the Milwaukee Journal Sentinel. (PX-380.) In that email, Dr. Stein states that he "officially broke ties" with five pharmaceutical companies, including Merck.

ARGUMENT

PLAINTIFFS SHOULD BE PRECLUDED FROM OFFERING EVIDENCE CONCERNING THESE THREE ISSUES BECAUSE IT WOULD BE IRRELEVANT AND UNFAIRLY PREJUDICIAL

I. Rule 401, 402, and 403 Standards

Under Rule 401 of the Federal Rules of Evidence, evidence is relevant if "(a) it has any tendency to make a fact more or less probable than it would be without the evidence; and (b) the fact is of consequence in determining the action." Fed. R. Evid. 401.

In determining whether evidence is relevant, courts consider whether there is a "logical chain of inference" moving from the evidence to one of the

parties' claims or defenses. *United States* v. *Sampson*, 980 F.2d 883, 888 (3d Cir. 1992). As this Court has ruled, "Relevancy 'exists only as a relation between an item of evidence and a matter properly provable in the case. Because the rule makes evidence relevant if it has any tendency to prove a consequential fact, it follows that evidence is irrelevant only when it has no tendency to prove the fact." *United States* v. *Brassington*, Crim. No. 09-CR-45(DMC), 2010 WL 3982036, at *16 (D. N.J. Oct. 8, 2010) (quoting *Spain* v. *Gallegos*, 26 F.3d 439, 452 (3d Cir. 1994)).

Under Rule 402, "[i]rrelevant evidence is not admissible." Fed. R. Evid. 402.

Under Rule 403: "The court may exclude relevant evidence if its probative value is substantially outweighed by a danger of one or more of the following: unfair prejudice, confusing the issues, misleading the jury, undue delay, wasting time, or needlessly presenting cumulative evidence." Fed. R. Evid. 403.

The probative value of evidence turns on "the extent to which it tends to demonstrate the proposition which it has been admitted to prove [and] the extent to which that proposition was directly at issue in the case." *Blancha* v. *Raymark Indus.*, 972 F.2d 507, 516 (3d Cir. 1992) (internal quotation omitted). "In balancing, the proper equation places on one side the maximum reasonable probative force for the offered evidence, while the other side of the equation

should include the likely prejudicial impact of the evidence." *Coleman* v. *Home Depot, Inc.*, 306 F.3d 1333, 1344 (3d Cir. 2002).

II. Evidence Concerning Separation Payments to Former Schering Executives and Concerning the Reasons for the Merck/Schering Merger Would Be Irrelevant and Unfairly Prejudicial, and Would Risk Confusing the Issues, Misleading the Jury, and Wasting Time

Merck and Schering agreed to merge fourteen months after they announced the results of the ENHANCE trial and nearly a year after the end of the class periods in these cases. There is no evidence in the record that the merger had anything at all to do with the ENHANCE trial. Any evidence concerning the reasons for the merger therefore has no relevance to any issue in these cases.

In addition, any evidence Plaintiffs may seek to elicit may be unfairly prejudicial and would risk confusing the issues, misleading the jury, and wasting time. Merck and Schering each disclosed its reasons for agreeing to the Merger in the Notice to their shareholders concerning the special meetings that were called to vote on the proposal to approve the merger agreement. (Notice of Shareholder Meeting) (Kravitz Aff. II __ at pp. 60-64, 70-73). Those disclosures are detailed and lengthy – about seven pages of text. Exploring those reasons would be a waste of time and could potentially mislead or confuse the jury into thinking that the merger was somehow related to the ENHANCE trial, when it was not.

In Herskowitz v. Nutri/Syst, Inc., 857 F.2d 179 (3d Cir. 1988), the Third Circuit affirmed on Rule 403 grounds the district court's exclusion of post-

merger financial performance to prove management's pre-merger intentions. The Third Circuit ruled that the district court "did not abuse its discretion in excluding [the evidence] under Fed. Evid. R. 403 on the ground that the possible prejudice arising from use of events long after the preparation of the proxy statement to cast light on the defendants' earlier intention outweighed its limited probative value."

Id. at 188.

Similarly, in *Patrick* v. *Patrick*, 2:08cv450, 2010 U.S. Dist. LEXIS 12402 (W.D. Pa. Feb. 12, 2010), the court ruled that evidence of a party's subsequent financial performance was irrelevant to the party's state of mind during the events at issue in the case. *Id.* at *15-19.

Here, similarly, the reasons for a merger that took place a year or more after the events at issue have no relevance to these cases and would likely be confusing and a waste of time.

The same is true of evidence concerning the separation payments to former Schering executives (including certain of the Defendants) in connection with the merger. That evidence has the additional potential for unfair prejudice because the substantial payments that these Defendants received may prejudice the jurors against them.

This Court dealt with a similar issue in Nye v. Ingersoll Rand Co.,
Consol. Civ. No. 08-3481 (DRD), 2011 U.S. Dist. LEXIS 130308 (D. N.J. Nov. 9,

2011). That case involved claims for benefits allegedly due to employees in connection with the sale of Dresser-Rand, a subsidiary of the defendant. Plaintiffs moved *in limine* to preclude evidence concerning a later IPO of Dresser-Rand and other post-sale compensation they received. This Court granted the motion, ruling:

The wealth or poverty of the parties is irrelevant to any issue in this case. Defendant would doubtlessly object if Plaintiffs sought to introduce evidence that it reported 14 billion dollars in net revenues last year. Defendant has offered no credible reason why the jury need be informed of the extent of Plaintiffs' earnings.

Id. at *24-25.

Similarly, in *Amboy Bancorporation* v. *Jenkins & Gilchrist*, 02-CV-5410 (DMC), 2008 U.S. Dist. LEXIS 62158 (D. N.J. Aug. 13, 2008), this Court granted the plaintiff's motion *in limine* to preclude evidence relating to the wealth of the plaintiff company and its officers, ruling:

This evidence does not relate to the facts to be proved, it will not aid the jury in its understanding of the case and it is not an element of any of [defendant's] affirmative defenses. As the personal wealth of the individuals does not further any of the claims or defenses in this action, the evidence is irrelevant and is, therefore, excluded.

Id. at *12-13.

Evidence concerning the substantial separation payments made to

Defendants who are former Schering executives should be excluded for the same reason.

III. Evidence Concerning the Salaries or Personal Wealth of Defendants or Employees of the Underwriters Is Irrelevant and Unduly Prejudicial

Like the evidence concerning the separation payments made to certain of the Schering Defendants, any evidence concerning the personal wealth or compensation generally of Defendants or employees of the Underwriters is also irrelevant and unfairly prejudicial, as this Court ruled in *Amboy Bancorporation*.

Courts routinely exclude such evidence as irrelevant and unfairly prejudicial. See, e.g., Draper v. Airco, Inc., 580 F.2d 91, 95 (3d Cir. 1978) ("Appealing to the sympathy of jurors through references to financial disparity is improper. . . . "[J]ustice is not dependent upon the wealth or poverty of the parties and a jury should not be urged to predicate its verdict on a prejudice against bigness or wealth."); Greenleaf v. Garlock, Inc., 174 F.3d 352, 364 n.9 (3d Cir. 1999) ("[I]t is improperly prejudicial for counsel to appeal to financial disparity between parties before the jury"); Brough v. Imperial Sterling Ltd., 297 F.3d 1172, 1178 (11th Cir. 2002) ("The general rule is that, during trial, no reference should be made to the wealth or poverty of a party, nor should the financial status of one party be contrasted with the other's.") (internal quotation omitted); Adams Labs., Inc. v. Jacobs Eng'g Co., 761 F.2d 1218, 1226 (7th Cir. 1985) ("If the wealth and size of a corporation are not at issue, counsel is bound to refrain from making reference to such size and wealth, or bear the risk of an unfavorable appellate reception.") (internal quotation omitted).

Accordingly, Plaintiffs should be precluded from offering any evidence concerning the wealth or compensation of Defendants or employees of the Underwriters. It is not relevant to any issue in these cases and would be unfairly prejudicial.

IV. Evidence Concerning Dr. Stein's Decision To "Cut Ties" Is Irrelevant And Unfairly Prejudicial

The evidence concerning Dr. Stein's decision to "cut ties" with Merck is also irrelevant and unfairly prejudicial.

It is irrelevant because his decision was unrelated to the ENHANCE trial. As PX-381 and Dr. Stein's testimony show, his decision was based on his own concerns regarding his academic independence and his reaction to allegations concerning Vioxx. It was unrelated to the ENHANCE trial. Moreover, even if his decision had been related to the ENHANCE trial, it would still be irrelevant. The jury is required to make its own determinations concerning Defendants' conduct. Dr. Stein's opinion in that regard is irrelevant.

Evidence concerning Dr. Stein's decision to "cut ties" would also be unfairly prejudicial, for at least two reasons. For one, his decision was based in part on allegations concerning Vioxx. As Defendants have argued in a separate *in limine* motion, evidence concerning Vioxx is irrelevant and unfairly prejudicial.²

See Defendants' Brief In Support Of Their Motion In Limine
 No. 1: To Preclude Plaintiffs From Offering Evidence Concerning Settlements,

And second, the jury should not be influenced by any opinions that Dr. Stein may have formed concerning Merck or Schering. It is the jurors' role to make their own determinations.

Accordingly, PX-380, PX-381, Dr. Stein's deposition testimony concerning his "cutting ties" with Merck and Schering, and any other evidence on that subject should be preluded.

CONCLUSION

For the reasons set forth above, Plaintiffs should be precluded from offering evidence concerning the Merck/Schering merger, and Dr. James Stein's decision to "cut ties" with Merck.

Dated: February 1, 2013

Respectfully submitted,

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Allegations Of Misconduct, And Other Matters Involving Vioxx And Other Drugs That Are Not At Issue In This Litigation.

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